Table of Contents

1.0 Description of the Service

Bioengineered skin is used to treat chronic wounds, burns, and rare skin conditions. These products promote the growth of new skin or serve as a temporary cover until other grafts can be placed. Bioengineered skin consists of a dermal layer and/or epidermal layer that is embedded into a cellular matrix forming the skin substitute.

Bioengineered skin substitutes have emerged as a potential alternative to skin grafting in cases of refractory, non-healing skin ulcers and burns. Various manufacturers produce bio-engineered skin substitutes, including but not limited to Apligraf, Integra, and Dermagraft. Each product is different and requires FDA approval for specific indications.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that limit the services available to them.

2.2 Limitations

Recipients are eligible for the procedure when they meet the medical necessity criteria listed in **Section 3.0.** If eligible, there are no age or gender restrictions.

2.3 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination****** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.

b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.0 When the Product Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

3.1 General Coverage Criteria

Medicaid covers bioengineered skin substitute when the procedure is medically necessary and:

a. the procedure is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;

b. the level of service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide;

c. the service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider; and

d. the product used has FDA approval.

3.2 Apligraf

3.2.1 Apligraf for Non-Infected Partial- and Full-Thickness Skin Ulcers

Apligraf is indicated for the treatment of non-infected partial and full-thickness skin ulcers due to venous insufficiency or neuropathic diabetic foot ulcers. The ulcer must be free of infection and underlying osteomyelitis, and treatment of the underlying disease must be provided and documented in conjunction with bioengineered skin substitute treatment.

3.2.2 Apligraf for Venous Stasis Ulcers

Medicaid covers Apligraf when all of the following conditions are met in the treatment of venous stasis ulcers and documented in the recipient's health record:

a. Ulcers are of more than three months' duration
b. Ulcers have failed to respond to documented conservative measures used for more than two months' duration (failed to decrease the ulcer by 50%).
c. Ulcers are partial or full thickness.
d. Measurement must be made of the initial ulcer size, the ulcer size following cessation of conservative management, and the size at the beginning of skin substitute treatment.
e. The ulcer must be free of infection and underlying osteomyelitis, and treatment of the underlying disease must be provided and documented in conjunction with bioengineered skin substitute treatment.

3.2.3 Apligraf for Neuropathic Diabetic Ulcers

Medicaid covers Apligraf when all of the following conditions are met in the treatment of neuropathic diabetic ulcers and documented in the recipient's health record:

a. Ulcers are of more than eight weeks' duration.
b. Ulcers have failed to respond to documented conservative measures used for more than two month's duration (failed to decrease the ulcer by 50%).
c. Ulcers are partial or full thickness.
d. Measurement has been made of the initial ulcer size, the ulcer size following cessation of conservative management, and the size at the beginning of skin substitute treatment.
e. Appropriate steps to off-load pressure during treatment are being taken.
f. The ulcer must be free of infection and underlying osteomyelitis, and treatment of the underlying disease must be provided and documented in conjunction with bioengineered skin substitute treatment.

3.3 Dermagraft for Full-Thickness Diabetic Foot Ulcers

Dermagraft is covered for the treatment of full-thickness diabetic foot ulcers when all of the following conditions are met:

a. The ulcer has persisted for six weeks or longer.
b. The ulcer extends through the dermis, but without tendon, muscle, joint capsule, or bone exposure.
c. The patient has adequate arterial blood supply to the foot.

d. The patient has a primary diagnosis of ICD-9-CM diagnosis codes 707.14 or 707.15 and a secondary diagnosis of diabetes in the range of ICD-9-CM diagnosis codes 250.80 through 250.83.

e. Ulcers are located on foot or toes and are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar, or any necrotic material that would interfere with adherence of a living skin equivalent and wound healing.

f. Patient's current HbA1C does not exceed 12%.

g. Dermagraft is used in conjunction with standard wound care regimens.

3.4 Bio-Engineered Skin for Burns

Medical necessity for the treatment of burns is established when both of the following conditions are met:

a. The product has full FDA approval

b. The product is used within the scope of the FDA indications

3.4.1 Integra

The application of Integra is covered when indicated for either of the following.

a. Postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient

b. Repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the patient

3.4.2 AlloDerm

The application of AlloDerm is covered when indicated for either of the following.

a. Skin grafting: AlloDerm is often used in conjunction with a split-thickness skin graft. AlloDerm is laid down first and is then covered by a thin split-thickness autograft. Both the application of AlloDerm and the split-thickness autograft are coded separately.

b. Plastic surgeries on various soft tissue defects, including abdominal wall reconstruction, breast reconstruction post-mastectomy, and tympanoplasty. Although reconstructive procedures require prior approval, the application of Alloderm does not.

4.0 When the Product Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

4.1 General Criteria

Bioengineered skin substitute is not covered when the criteria listed in Section 3.0 are not met. Bioengineered skin substitute is not covered when:

a. the procedure duplicates another provider's procedure in a way or frequency that is not medically necessary.
b. the procedure is experimental, investigational, or part of a clinical trial; or
c. the bioengineered skin substitute does not have FDA approval.

4.2 Specific Criteria

The use of bioengineered skin substitute is not covered for these diagnoses and conditions:

a. Infected ulcer
b. Ulcers with sinus tracts
c. Osteomyelitis
d. Patients with known hypersensitivity to bovine products
e. Arterial disease with an ankle brachial index (ABI) (systolic ankle blood pressure over the systolic brachial blood pressure) of less than .65 in the case of venous stasis ulcers, or a lack of pedal pulses in the case of neuropathic diabetic foot ulcers
f. Uncontrolled diabetes (for purposes of this policy, controlled diabetes is based on documentation in the medical record)
g. Active Charcot's arthropathy of the ulcer extremity
h. Vasculitis
i. Uncontrolled rheumatoid arthritis and/or rheumatoid ulcers
j. Other uncontrolled collagen vascular diseases
k. Patients under treatment with high-dose corticosteroids or immunosuppressants
l. Patients who have undergone radiation and/or chemotherapy within the month immediately preceding proposed skin substitute treatment

The application of Integra is not covered for these diagnoses and conditions:

a. Patients with known hypersensitivity to bovine collagen or chondroitin materials
b. All other applications not listed in **Section 3.4.1** as medically necessary

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health

in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

5.1 General Limitations

a. Apligraf coverage is limited to 88 units within 365 days.

b. Dermagraft coverage is limited to 150 units/day to a maximum of 300 units every twelve weeks.

c. Integra coverage is limited to the application of a quantity of material that closely approximates the size of the wound. The number of units billed, must closely correlate with the wound size. The maximum daily allowable units are 60.

5.2 Venous Stasis Ulcers

The following limitations apply to the treatment of venous stasis ulcers.

a. There can be no fewer than six weeks between applications.

b. Two applications of skin substitute are indicated. A third application of skin substitute will be considered for coverage if a 50% or greater improvement is noted and documented. Documentation must be submitted.

c. Re-treatment within one year of initial treatment is not covered.

5.3 Neuropathic Diabetic Ulcers

The following limitations apply to the treatment of neuropathic diabetic foot ulcers.

a. There can be no fewer than three weeks between applications.

b. Reapplication of the skin substitute is not recommended after three applications when satisfactory healing progress is not noted (that is, a 50% or greater improvement). Other treatment modalities should be considered.

6.0 Providers Eligible to Bill for the Service

Providers who meet Medicaid's qualifications for participation and are currently enrolled with the N.C. Medicaid program are eligible to bill for these services when the services are within the scope of their practice.

7.0 Additional Requirements

The medical record must show that criteria described in Section 5.0 and Section 3.0 have been met and must document that wound treatment by this method is accompanied by

a. appropriate wound dressing during the healing period;

b. appropriate compressive dressings during follow-up; and

c. appropriate steps to off-load wound pressure during follow-up (for neuropathic diabetic foot ulcers).

8.0 Policy Implementation/Revision Information

Original Effective Date: November 1, 2000

Revision Information:

Date	Section Updated	Change
4/1/07	Throughout policy	Implementation of coverage for the application of Integra

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Physicians, emergency department physicians, medical clinics, and nurse practitioners enrolled in the N.C. Medicaid program bill services on the CMS-1500 claim form. Hospitals and hospital outpatient services bill on the UB-92 claim form.

B. Diagnosis Codes That Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis that most accurately describes the reason for the encounter. Diagnostic codes must be billed at their highest level of specificity.

Apligraf

ICD-9-CM Code	Description
250.60 through 250.61	Diabetes, with neurological manifestations
250.80 through 250.83	Diabetes, with other specified manifestations. Use additional code to identify manifestation 707.10 through 707.19.
454.0	Varicose veins of lower extremities, with ulcer
454.2	Varicose veins of lower extremities, with ulcer and inflammation
707.10 through 707.19	Ulcer of lower limb, except decubitus. ICD-9-CM codes 250.80 through 250.83 must be reported with these codes.

Dermagraft

ICD-9-CM Code	Description
707.14 or 707.15	Ulcer of lower limb, except decubitus. ICD-9-CM codes 250.80 through 250.83 must be reported with these codes.
250.60 through 250.61	Diabetes, with neurological manifestations
250.80 through 250.83	Diabetes, with other specified manifestations. Use additional code to identify manifestation 707.10 through 707.19.

C. Procedure Code(s)

Apligraf and Dermagraft must be billed in conjunction with codes that describe application of the tissue and preparation of the site. For burn treatments, reimbursement for physician services is limited to the application of the product.

1. HCPCS Procedure Code

J7340—Apligraf
J7342—Dermagraft

2. CPT Procedure Codes

15002 through 15005 may be used to bill for the site preparation. Bill on the CMS 1500 form using HCPCS procedure code listed above.

D. Billing Units

One unit equals 1 sq. cm.

Date of Service	Code	Description
January 1, 2007, and after (replaces 15000)	15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar; or incisional release of scar contracture, trunk, arms, legs, first 100 sq cm or 1% of body area of infants and children (one unit)
January 1, 2007, and after (replaces 15001)	15003	Each additional 100 sq cm or 1% of body area of infants and children (in addition to primary code).(60 units)
January 1, 2007, and after	15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar; or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children (one unit)
January 1, 2007, and after	15005	Each additional 100 sq cm or 1% of body area of infants and children (in addition to primary code) (20 units)
January 1, 2006, and after	15170	Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children **use for the application of Integra** (one unit)
	15171	each additional 100 sq cm, **use for the application of Integra** (60 units)
	15175	Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less **use for the application of Integra** (one unit)
	15176	each additional 100 sq cm, use for the application of Integra (20 units)
	15330	Acellular dermal allograft, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children **use for the application of Alloderm** (one unit)
	15331	each additional 100 sq cm, or each additional one percent of body are of infants and children, or part thereof **use for the application of Alloderm** (three units)
	15335	Acellular dermal allograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less or one percent of body area of infants and children (1 unit)
	15336	each additional 100 sq cm, or each additional one percent of body are of infants and children, or part thereof (three units)
	15340	Tissue cultured allogeneic skin substitute; first 25 sq cm or less **use for the application of Apligraf** (one unit)

Date of Service	Code	Description
	15341	Tissue cultured allogeneic skin substitute; each additional 25 Sq cm **use for the application of Apligraf** (three units)
	15360	Tissue cultured allogeneic dermal substitute; trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children **use for the application of Apligraf/Dermagraft** (one unit)
	15361	Tissue cultured allogeneic dermal substitute; each additional 100 sq cm, or each additional one percent of body are of infants and children, or part thereof **use for the application of Apligraf/Dermagraft**(three units)
	15365	Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first100 sq cm, or less or one percent of body area of infants and children **use for the application of Apligraf/Dermagraft** (one unit)
	15366	Tissue cultured allogeneic dermal substitute; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof **use for the application of Apligraf/Dermagraft** (three units)
	J7340	Apligraf
	J7342	Dermagraft

E. Place of Service

Place of service for Dermagraft and Apligraft is limited to inpatient, outpatient hospital, and office. Place of service for Integra and Alloderm is limited to inpatient and outpatient hospital.

F. Modifiers

Providers are required to follow modifier guidelines.

G. Reimbursement Rate

Providers must bill their usual and customary charges.